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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,694	08/07/2001	Atsushi Suzuki	210377US0	8724

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EXAMINER	
HAWES, PILI ASABI	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,694	SUZUKI ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Action Summary

This office action is responsive to applicants remarks filed 07-11-2005.

Claims 1-39 have been cancelled. New claims 40-68 are pending in this action. Claims 40-68 are rejected.

Double Patenting

The double patenting rejection is maintained in abeyance.

Claims 40-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,310,100 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose treatments for hypertension comprised of ferulic acid or a derivative thereof. The therapeutic compositions comprising ferulic acid and its derivatives may further comprise pharmaceutical products, nutritional supplements or products, and foods. The reference does not specifically claim chlorogenic or caffeic acid in combination with ferulic acid, but in claim 5 it does disclose a composition "consisting essentially of ferulic acid or a derivative thereof, and at least one other anti-hypertensive compound," which would encompass chlorogenic and caffeic acid. One of ordinary skill in the art would be motivated to combine chlorogenic and caffeic acids, which are known anti-hypertensive agents to a composition comprising ferulic acid with the expectation of successful treatment of hypertension with such a composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40, 46 and all claims that depend therefrom are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not support the language "isolated or purified" and is therefore considered **new matter**. The specification does support extraction from a natural substances. Herbal extracts are not necessarily purified, and may contain various other active and inactive species within the extracted liquor. The specification does not use the language isolated or purified, nor is the process of isolating or purifying the specific compound disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-68 are rejected under 35 U.S.C 103(a) as being unpatentable over Abraham (XP-001148404, 1996) in view of Hsu (US 5,958,417) and further in view of Ghai et al. (US 5,955,269). The claims are to a composition consisting essentially of ferulic acid and caffeic acid, chlorogenic acid or a combination of caffeic acid and chlorogenic acid. Abraham discloses a dietary constituent comprising a combination of chlorogenic acid, caffeic acid and ferulic acid (Table 1). These phenolic compounds occur in some of the commonly consumed vegetables, fruits and beverages (page 19, column 1). Abraham does not expressly disclose that the referenced dietary constituents are used in the treatment of hypertension. However, Hsu ('417) addresses this limitation by disclosing that the active principles, chlorogenic acid and caffeic acid, found in the herbal substance, Crataegus, are used to treat hypertension (column 2, lines 59-61).

One of ordinary skill in the art would have been motivated to combine the dietary constituents disclosed by Abraham to make a composition for treatment of hypertension

as discussed by Hsu because of the need for alternatives to conventional pharmaceuticals currently used to treat hypertension, with an expectation of fewer harmful side effects.

The examiner cites Ghai et al. (US 5, 955,269) that discloses processed foods, or foods fortified with nutraceuticals and the methods of adjusting the combination and level of these nutraceutical compounds in a supplement or in food products to achieve added nutritional or therapeutic benefit (col. 25, lines 1-3, col. 26, lines 43-50 and col. 27, lines 19-25). The reference further teaches that nutraceutical compounds can be administered by inhalation; orally as tablets, capsules, or liquid preparations; controlled release formulations; or as food supplements (col. 25-26). Table 1 (col. 23, lines 41-65) further discloses examples of phenolic acids, such as caffeic, chlorogenic, and ferulic acids as examples of food substances that can be used as nutraceuticals. The reference does not disclose the anti-hypertensive properties of caffeic, chlorogenic, or ferulic acids. However, the teachings of Hsu, as discussed above, do address this limitation. It would have been obvious to one of ordinary skill in the art to combine ferulic acid with chlorogenic acid and caffeic acid as taught by Ghai to obtain synergistic effects in the treatment of hypertension. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a nutraceutical supplement to fortify foods or beverages as taught by Ghai, and to use said foods or beverages in the treatment of hypertension as taught by Hsu, with an expectation of reduced toxicity.

Response to Arguments

The rejections as set forth in the previous office action are maintained. As was stated above in the 112 rejections, the new claimed limitation "isolated or purified" is not supported by the specification. Therefore this limitation is not limiting with respect the examination of the claims.

Applicants' amendment to claim 40 to include the language "consisting essentially of" is acknowledged. It would be obvious to make a composition consisting essentially of ferulic, chlorogenic, and caffeic acid, based on the teaching of Abraham. Applicants argue that Abraham does not teach a composition consisting essentially of ferulic acid, chlorogenic, or caffeic acid for the treatment of high blood pressure. However, Abraham does teach a composition comprising these active ingredients. A compound and its properties cannot be separated. Ferulic acid, chlorogenic acid, and caffeic acid in the composition taught by Abraham would have been able to impart hypertensive effects in a patient in need thereof.

Hsu teaches Crataegus to be effective in treating hypertension and also discloses the active principles contained in the herb. It would be reasonable to conclude that active ingredients selected from this group would yield anti-hypertensive effects. Applicants argue that there would be no reasonable expectation of success for combining ferulic, chlorogenic, and caffeic acid to reduce high blood pressure. Abraham teaches to combine them, and Hsu teaches their properties as anti-hypertensive agents. Use of these active ingredients alone or in combination would yield anti-hypertensive effects; therefore it would be reasonable to expect success in combining them.

Applicants disclose in Table 1 the combination of these active ingredients but there are no unexpected results. There are no additive or synergistic effects from the combination of these active ingredients. Caffeic acid alone yields a reduction –4.1%, chlorogenic acid a reduction –3.2%, and ferulic acid alone a reduction of –7.8%. Additive effects would be to see a reduction in systolic blood pressure –15.1% when the three were combined. However the three combined yield less than additive effect, with a reduction of –11.1% in systolic blood pressure. Also applicants have not shown a reduction in diastolic blood pressure, claims to this effect are not supported by the disclosure.

Ghai teaches the addition of nutraceutical compositions into processed foods or food substances. One of ordinary skill in the art would be able to readily envision that processed foods or food substances refer to the particular food products recited by applicant, such as milk products, cereal, pasta, soy, wheat, rice, or oil/fat containing foods. As was previously discussed, the teachings of Abraham and Hsu would make the composition containing the active principles, ferulic, chlorogenic, and caffeic acid for the treatment of hypertension obvious. It would further be obvious to use this nutraceutical composition to fortify processed foods and food substances as Ghai teaches.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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